## REMARKS

### THE INVENTION

This invention relates to the use of glucocorticoid receptor antagonists [GRA] for the treatment of postpartum psychosis [PPP]. Although GRAs have been disclosed for treating the psychotic feature of psychotic major depression and other psychiatric disorders, GRAs have not been previously disclosed as useful for treating PPP.

### STATUS OF THE CLAIMS

Claims 1-11 and 15 are pending. The pending claims are rejected as obvious.

### REJECTIONS

**35 U.S.C. §103(a).**

The pending claims 1-6, 9-11 and 15 are rejected as obvious over Schatzberg U.S. Pat. No. 6,150,349 ('349) and Stowe. The '349 patent was co-invented by Dr. Belanoff, the sole inventor of the subject application. The '349 patent taught the use of GRAs for treating the psychotic symptom of psychotic major depression. GRA's do not affect the depressive symptoms of this disorder. The '349 patent provides a general definition of psychosis in columns 14-15. The definition is derived from the Diagnostic and Statistical Manual of Mental Disorders (attached as **Exhibit 1**). In the definition from the DSM IV, the DSM authors provide a subclassification of various psychotic disorders that are not well understood and do not meet other DSM IV categories. Among these psychotic disorders is PPP (see column 15, at lines 54-55).

While the '349 patent provides a broad definition of psychosis, a fair reading would not lead a reader to conclude that it taught the use of GRAs for treating any and all forms of psychosis. The '349 patent addresses only psychotic major

depression. Psychotic major depression is distinct from other disorders involving psychotic features such as schizophrenia, schizoaffective disorder, brief psychotic disorder, post-traumatic stress disorder and PPP. Because they are distinct disorders having unknown or different etiologies, the cure for one disorder does not motivate one of skill to try the cure for another disorder with the requisite expectation of success required for a *prima facie* case of obviousness.

Furthermore, it is important for the Examiner to understand that psychotic major depression is not a severe form of major depression. Most people with clinical depression never become psychotic. When psychoses does appear, doctors believe that a distinct disorder has arisen. **Exhibits 2** and **3** provide evidence of this fact. Glassman (**Exhibit 2**) in 1980 writes that clinical depression and psychotic major depression have many differences that suggest that they are distinct psychiatric disorders. In 1992 , Schatzberg and Rothchild published further evidence (see **Exhibit 3**). By 1999, the medical community and textbooks had accepted them as distinct disorders (see **Exhibit 4** - Textbook of Psychiatry @ page 493).

Stowe et al. is relied upon for disclosing postpartum depression. Stowe distinguishes between postpartum depression and postpartum psychosis and clearly states on page 639, column 2, that they do not intend to discuss postpartum psychosis in any detail. Indeed, there is only sparse reference to PPP in the Stowe article. At page 640, at column 2, there is mention of a publication disclosing a relationship between growth hormone response and PPP. Applicant could find no further mention of PPP in Stowe.

The Examiner appears to have confused postpartum depression [PPD] with post-partum psychosis [PPP]. They are distinct medical disorders. Again, PPP is not a severe form of PPD. Mothers without PPD can suffer from PPP. Three references are provided to support this medical understanding. **Exhibit 5**, Kaplan and Sadocks Comprehensive Textbook of Psychiatry has a chapter 13.4 on postpartum psychiatric disorders. On page 1278, the authors identify three common postpartum disorders: blues, depression, and psychosis. There is simply no suggestion in the text book that

these are related disorders beyond the obvious connection to postpartum mothers. **Exhibit 6** from Peace and Healing website states in the first sentence defining PPP that PPP is not a variant of postpartum depression but a distinct entity. Finally, **Exhibit 7** is a lay article from National Public Radio. It is a dramatic story of one mother's painful experience with PPP. She explains that her psychotic episode arose without warning (page 2) or depression. Her fear of recurrence forced a decision not to have more children.

There is no agreement in the medical community concerning the etiology of either postpartum depression or PPP. Stowe expressly ends with a statement that postpartum depression is not understood. They write on page 644, "Although the cause of PPD remains an enigma, there is sufficient evidence to support multifactorial contribution to its development." The same can be said for PPP.

A proper *prima facie* case of obviousness requires the Examiner to identify from the prior art suggestion or motivation to treat mothers with PPP using GRAs with an articuable expectation of success. The Schatzberg and Belanoff '349 patent does not set forth this suggestion expressly or impliedly. The fact that the psychotic features of psychotic major depression are treatable with GRAs does not lead one of skill to conclude that GRAs would be useful to treat PPP. It is an accepted fact that not all psychoses are treatable by GRA therapy. For example, GRAs are of no benefit to schizophrenic patients.

Unless the Examiner can find prior art supporting a medically accepted link between the causes of psychotic major depression and PPP, there can be no *prima facie* case of obviousness based on Schatzberg even when combined with the Stowe publication discussing postpartum psychosis in passing.

Claim 7 reciting specific GRAs is rejected as obvious in view of Schatzberg, Stowe and Bradley. Schatzberg and Stowe are relied upon for the teachings set forth above, and Bradley is relied upon for disclosing specific GRAs.

Applicant relies on the arguments set forth above for independent claim 1. Schatzberg and Stowe do not set forth a proper *prima facie* case of obviousness and the addition of Bradley's recitation of GRAs does not lend further support to the Examiner's position. If claim 1 is nonobvious over Schatzberg and Stowe, all the dependent claims must be non-obvious.

CONCLUSION

In view of the foregoing, applicant submits that the *prima facie* case of obviousness has not been properly set forth and that the rejection should be withdrawn. The claims are believed to be in condition for allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, he is invited to call the undersigned attorney at the number provided.

Respectfully submitted,



Kenneth A. Weber
Reg. No. 31,677

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
KAW:kaw/jhd

Attachments: Exhibits 1-7

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